

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

UNITED STATES OF AMERICA,

v.

**(1) STRYKER BIOTECH, LLC,
(2) MARK PHILIP,
(3) WILLIAM HEPPNER,
(4) DAVID ARD and
(5) JEFFREY WHITAKER,**

Defendants.

Criminal No: 09-CR-10330-GAO

**LEAVE TO FILE GRANTED
DECEMBER 12, 2011**

ORAL ARGUMENT REQUESTED

**DEFENDANT STRYKER BIOTECH'S REPLY
IN SUPPORT OF ITS MOTION TO DISMISS COUNT 13**

In its Opposition to Stryker Biotech's motion to dismiss Count 13, the Government relies on arguments that federal courts already have rejected and that, if accepted, would turn 18 U.S.C. § 1001 into a strict liability statute with respect to corporate defendants, a radical result that Congress could not have intended and that would raise substantial constitutional questions.

Stryker Biotech's motion to dismiss is not, as the Government asserts, premature. Rather, the Government concedes in its Opposition that it will seek to prove Stryker Biotech's *mens rea* by aggregating the states of mind of multiple individual employees, a theory of criminality that the Court can and should deem invalid as a matter of law. *See* Fed. R. Crim. P. 12(b)(2) (standard for pre-trial dismissal). And although the Government asserts in passing that it "expects to adduce evidence at trial in support of" two other "options" for proving *mens rea*, Gov't Opp. at 10-11, neither of those two "options" is contained in the Superseding Indictment,

and the Court therefore can and should hold that the Fifth Amendment's Presentment Clause bars the Government from proceeding to the jury on them. *See* Fed. R. Crim. P. 12(b)(2).

Not only are the Government's arguments insufficient to defeat Stryker Biotech's motion to dismiss, but they also confirm that the Government has no objectively reasonable expectation of proving beyond a reasonable doubt the Superseding Indictment's conclusory allegation that the supposed falsification of the 2007 Annual Report was an overt act performed with the calculated intent to further the separate fraud conspiracy charged in Count 1. Accordingly, regardless of the resolution of Stryker Biotech's motion to dismiss, the Court should hold that Count 13 is not properly joined under Rule of Criminal Procedure 8(b) and grant Defendants' pending severance motions.

ARGUMENT

I. The Government's Reading of *Bank of New England* Already Has Been Rejected.

Section 1001 specifically requires proof that a defendant acts both "knowingly and willfully." The Government, however, reads "willfully" right out of the statute, directly contrary to the Supreme Court precedent. *See Ratzlaf v. United States*, 510 U.S. 135, 140-41 (1994) (vacating conviction where the district court's jury instructions treated the statutory element of "'willfulness' [] essentially as surplusage"). The Government's Opposition proposes the following syllogism: **(i)** *United States v. Gonsalves* holds that Section 1001's "willfulness" element "means nothing more . . . than that the defendant knew that his statement was false when he made it," **(ii)** *United States v. Bank of New England* holds that a corporation's "knowledge" is the "aggregate knowledge of all of its employees," and therefore **(iii)** a corporation violates Section 1001 if it makes a statement to a federal agency that contradicts facts of which any of its employees has knowledge. Gov't Opp. at 7-10.

The Government's vision of Section 1001 would result in an unprecedented and potentially unconstitutional expansion of the statute's reach. With respect to a corporate defendant, the Government's position would effectively eliminate "the requirement of a 'guilty mind,'" transforming Section 1001 into a "strict liability" statute under which a corporation will be exposed to the penalties and stigma of a felony false statement conviction even where its employee *inadvertently* made an inaccurate statement to a federal agency.¹ *Staples v. United States*, 511 U.S. 600, 607 n.3 (1994). The constitutionality of such a result would be substantially questionable. *See United States v. Apollo Energies, Inc.*, 611 F.3d 679, 688 n.4 (10th Cir. 2010) ("[D]ue process suggests some constitutional limits on the penalties contained in strict liability crimes. Severe fines and jail time would warrant a state of mind requirement."). The Court must therefore presume that Congress did not intend it. *See United States v. X-Citement Video*, 513 U.S. 64, 68-69 (1994) (holding that a criminal statute's *mens rea* element "is to be construed where fairly possible so as to avoid substantial constitutional questions").

Not surprisingly, the Government fails to cite a single case that actually supports its proposed aggregation method of establishing that Stryker Biotech "knowingly and willfully" made a false statement to a federal agency. In fact, the D.C. Circuit rejected an identical argument in *United States v. Science Applications International Corp.*, 626 F.3d 1257 (D.C. Cir. 2010). In *Science Applications*, the district court instructed the jury that, under the False Claims Act, a corporation acts with *scienter* if "at least one individual employee . . . ha[s] actual knowledge" of facts that "contradict[] . . . the statements and claims" that the corporation makes as part of submitting a claim for payment to the federal government. *Id.* at 1273. In

¹ Indeed, under the Government's view of the law, a corporation might violate Section 1001 almost every time it files inaccurate information with a federal agency, as it will nearly always be possible for the government to find at least one employee who knew the "correct" information.

unsuccessfully seeking to defend this jury instruction on appeal, the Department of Justice “relie[d] primarily on . . . *Bank of New England*.” *Id.* at 1275.

The DOJ’s argument in *Science Applications* was that (i) a corporation acts with *scienter* under the False Claims Act if it “knowingly” makes a false statement to a federal agency as part of a claim for reimbursement, (ii) *Bank of New England* endorses the concept of “collective knowledge,” and therefore (iii) *scienter* under the False Claims Act can be established by “aggregating the states of mind of multiple [employees].” *Id.* at 1274. The D.C. Circuit rejected the DOJ’s argument, holding that, under *Bank of New England*, “proof of the proscribed intent . . . [still] depend[s] on the wrongful intent of specific employees.” *Id.* at 1275 (quoting *Saba v. Compagnie Nationale Air France*, 78 F.3d 664, 670 n.6. (D.C. Cir. 1996)). The D.C. Circuit made clear that False Claims Act liability cannot attach to a corporation “absent proof that [specific] corporate officials acted with deliberate ignorance or reckless disregard for the truth.” *Id.* The D.C. Circuit found it legally irrelevant that the False Claims Act’s “proscribed intent” is defined in terms of “knowledge.” *Id.* at 1275-76.

The Government’s Opposition does not assert that *Science Applications* is wrongly decided. Instead, the Government simply dismisses *Science Applications* as “inapposite.”² See Gov’t Opp. at 8. Contrary to the Government’s belief, *Science Applications* is in fact squarely on point. The False Claims Act’s *scienter* requirement of “knowingly” is materially identical to Section 1001’s *mens rea* element of willfulness, which, to use the Government’s own words,

² The Government treats in a similarly dismissive fashion the several other cases cited in Stryker Biotech’s opening brief that reject the use of “aggregation” theories to establish a corporation’s *mens rea*. Compare Def.’s Mem. L. Supp. Mot. Dismiss at 6-7 with Gov’t Opp. at 8-9. At bottom, the Government’s position appears to be that Section 1001 should simply be treated differently than other civil and criminal statutes that contain *mens rea* or *scienter* elements.

“has a knowledge-based meaning.” Gov’t Opp. at 9.³ Logically, if “aggregating” the disparate knowledge possessed by multiple corporate employees is not a permissible means of establishing *scienter* under the civil False Claims Act, it cannot be a permissible means of establishing *mens rea* under Section 1001. Consistent with *Science Applications*, the Court should hold that the Government can convict Stryker Biotech on Count 13 only if it proves beyond a reasonable doubt “the wrongful intent of specific employees.” *Sci. Applications*, 626 F.3d at 1275.

II. The Government’s Opposition Fundamentally Misapprehends and Misapplies *Bank of New England’s* “Collective Knowledge.”

The Government’s argument here is not only inconsistent with *Science Applications*, but also fundamentally misapprehends and misapplies the “collective knowledge” concept that *Bank of New England* itself endorsed. In *Bank of New England*, the First Circuit affirmed a jury instruction that explained merely that the “knowledge” of a corporation “is the sum of the knowledge of all of the employees.” 21 F.2d at 855. Applying that unremarkable jury instruction to the critical *mens rea* element of a Section 1001 charge, a corporation is guilty of violating Section 1001 if one of its individual employees *knew* that the corporation was making a false statement to a federal agency at the time the statement was made.

In this case, the Government advances a radically different version of “collective knowledge.” The Government proposes that Stryker Biotech “knowingly” made a false statement to the FDA so long as (1) the 2007 Annual Report contained an inaccurate statement regarding the number of patients treated with OP-1 Putty, and (2) some Stryker Biotech employee knew the “correct” number of patients treated with OP-1 Putty. The Government

³ Tellingly, in the sentence immediately preceding its dismissive treatment of *Science Applications*, the Government cites the First Circuit’s pattern instruction on Section 1001’s *mens rea* element. See Gov’t Opp. at 8. That pattern instruction tracks essentially word-for-word the False Claims Act’s statutory definition of “knowingly.” Compare First Circuit Pattern Instructions, 4.18 (1998) (Section 1001 *mens rea* element) with 29 U.S.C. § 3729(b)(1) (defining “knowingly” under the False Claims Act).

believes it is entirely irrelevant whether, at the time the 2007 Annual Report was filed, the Stryker Biotech employee who knew the “correct” number *also knew* that the 2007 Annual Report contained an inaccurate number. To this extent, the Government is not seeking merely to “aggregate” or “collect” the knowledge of Stryker Biotech’s employees. Instead, the Government is seeking to *create* in the figurative “mind” of Stryker Biotech a specific and essential piece of knowledge that the Superseding Indictment does not allege *any* individual Stryker Biotech employee possessed at the time the 2007 Annual Report was filed: namely, knowledge that the report contained a false statement. *Bank of New England* does not remotely support such a thing.⁴

The Government fares no better with its alternative argument that Stryker Biotech violated Section 1001 because “having information at various levels of the company about the real usage of OP-1 Putty, the company consciously disregarded or averted its eyes from the [2007 Annual Report’s] likely falsity.” Gov’t Opp. at 7-8. It is black letter law “that corporations cannot in and of themselves possess a mental state.” *United States v. Investment Enters.*, 10 F.3d 263, 266 (5th Cir. 1993). Thus, to establish that Stryker Biotech acted with “conscious disregard” in connection with the filing of the 2007 Annual Report, the Government must establish that at least one of the company’s *individual employees* acted with that state of mind in connection with the filing.⁵ The Superseding Indictment, however, does not contain any such allegation.

⁴ If the Court were to accept the Government’s radical proposal, it would result in precisely the same constitutional infirmities that Stryker Biotech discussed earlier in this brief (see page 3 *supra*).

⁵ *Bank of New England* is not to the contrary. In that case, the First Circuit emphasized that the prosecution had proved that specific individual employees knew that the bank had to report certain currency transactions and “suspected that [bank customer McDonough] was [illegally] structuring his transactions to avoid [triggering those] reporting requirements,” yet chose to look the other way because

III. The Fifth Amendment's Presentment Clause Bars the Government From Advancing New Factual Bases for Count 13 in Response to Pre-trial Motions.

As alternatives to its legally invalid “collective knowledge” theory,⁶ the Government offers as an afterthought two additional “options” for proving Count 13. The Government states that it “expects to adduce evidence at trial” that (1) “one of the Stryker employees knew that the statements in the [2007] annual report were false” or (2) “one of the Stryker employees consciously disregarded or averted his eyes from its likely falsity.” Gov’t Opp. at 10-11. The Government’s Opposition acknowledges that, relative to its “collective knowledge” theory, these two additional “options” constitute entirely distinct legal and factual theories by which Stryker Biotech might have committed the essential elements of a Section 1001 violation.

The Government’s assurances about what it “expects to adduce” at trial are insufficient to save Count 13 from pre-trial dismissal. Although it has repeatedly asserted that it has provided Defendants with a “roadmap” to its case, the Government has failed to provide any evidence in discovery that some individual Stryker Biotech employee acted “knowingly and willfully” in connection with the filing of the 2007 Annual Report. Nor has it provided any evidence that some individual Stryker Biotech employee “consciously disregarded” the truth or falsity of the 2007 Annual Report when it was filed. This lack of evidence explains why Count 13’s charging paragraphs refer generically to “Stryker Biotech” and fail to identify a single individual Stryker Biotech employee (by name, title, or otherwise) as having acted with a criminal *mens rea* in connection with the filing of the 2007 Annual Report. *See* Superseding Indictment, ¶¶ 66-68.

McDonough was a “good customer.” *Bank of New England*, 821 F.2d at 857 (holding that this evidence was sufficient to sustain a jury’s finding of “flagrant indifference to the obligations imposed by the Act”).

⁶ Whether one calls the Government’s aggregation theory “collective knowledge” or “collective intent” is ultimately beside the point. Whichever nomenclature is used, it remains the case that the Government’s aggregation theory finds no support in law or logic.

The face of the Superseding Indictment does not afford any basis on which the Court could conclude that the grand jury was presented with and endorsed the factual allegation that some individual Stryker Biotech employee acted either “knowingly and willfully” or with “conscious disregard” in connection with filing of the 2007 Annual Report. Instead, the manner in which Count 13 is charged indicates that the Government presented the grand jury solely with the legally invalid “collective knowledge” theory. At a bare minimum, it would be pure speculation to suggest that the grand jury indicted Stryker Biotech on Count 13 on any basis other than the Government’s legally invalid “collective knowledge” theory. Thus, to allow the Government to proceed to trial on anything other than the “collective knowledge” theory would violate the Constitution’s Presentment Clause. *See Russell v. United States*, 369 U.S. 749, 770 (1962) (“To allow the prosecutor . . . to make a subsequent guess as to what was in the minds of the grand jury at the time they returned the indictment would deprive the defendant of a basic protection the guaranty of the intervention of a grand jury was designed to secure.”); *United States v. Robles-Vertiz*, 155 F.3d 725, 728 (5th Cir. 1998) (“[T]he government may not obtain an indictment alleging certain material elements or facts of the crime, then seek a conviction on the basis of a different set of elements or facts.”); *United States v. Scott*, 243 F. Supp. 2d 97, 102 (D. Del. 2003) (“A constructive amendment to an indictment occurs when a case is submitted to a jury on a theory that is not contained in the indictment.”).

To be sure, when an indictment explicitly charges “the commission of one offense in several ways,” a court is allowed to “withdraw[] from the jury’s consideration . . . one alleged method of committing” the charged offense without violating the rule against constructive amendments. *United States v. Miller*, 471 U.S. 130, 145 (1985); *see United States v. Mubayyid*, 658 F.3d 35, 50 (1st Cir. 2011) (allowing variances that “add[ed] nothing new to the grand jury’s

indictment”). That rule has no application here, where there is no indication that the Government even presented the grand jury with any legally valid ground for indicting Stryker Biotech on Count 13 in the first place. Thus, not only does the Government’s post-indictment claim that a specific, though still unnamed, Stryker Biotech employee acted with criminal *mens rea* in connection with the filing of the 2007 Annual Report “add something new” to the Superseding Indictment,⁷ but it also constitutes a post-indictment attempt to “cure” a felony charge that was, as a matter of law, fatally defective when it was issued. *Cf. United States v. Covino*, 837 F.2d 65, 72 n.2 (2d Cir. 1988) (“The government has on appeal speculated upon theories that might render the facts in this case consistent with *McNally*. However, the indictment clearly did not charge Covino [with those theories].”).

When the government wishes to charge a corporation with a felony false statement based on the criminal wrongdoing of a specific employee, it does not use charging language that, as here, omits all mention of that individual employee. For example, in *United States v. Robison*, the indictment’s false statement charge against McWane, Inc. explicitly alleged that McWane’s president of environmental affairs, Charles Robison, was the employee who made the allegedly false statement to the Environmental Protection Agency. *See Robison*, 505 F.3d 1208, 1227 (11th Cir. 2007) (quoting the indictment’s false statement charge against McWane, Inc.).⁸ By contrast, Count 13 refers generally to “Stryker Biotech” and does not contain any allegation that

⁷ Because the Government’s legally invalid “collective knowledge” theory is explicitly premised on the idea that Stryker Biotech violated Section 1001 even if *none* of its individual employees acted with criminal *mens rea* in connection with the filing of the 2007 Annual Report, the grand jury’s return of Count 13 on the basis of that “collective knowledge” theory does not imply a grand jury finding that an individual Stryker Biotech employee acted with criminal *mens rea* in connection with the filing of the 2007 Annual Report.

⁸ Stryker Biotech discussed *Robison* at page 8 of its opening brief, but the Government did not address *Robison* in its opposition.

an individual Stryker Biotech employee acted with criminal *mens rea* in connection with the filing of the 2007 Annual Report.

Having plainly proceeded in the grand jury on the basis of its legally invalid “collective knowledge” theory, the Government cannot now be allowed to construe Count 13’s generic term “Stryker Biotech” as a mere placeholder that, to the extent its “collective knowledge” theory is held legally invalid, it promises to fill with a specific Stryker Biotech employee whose identity the Government may reveal at some later date. *See United States v. Hitt*, 249 F.3d 1010, 1019 (D.C. Cir. 2001) (holding that a court “must construe [an] indictment in light of its principal purposes of clarity and notice” and citing the Supreme Court’s decisions in *Russell* and *Stirone*). Not only did the grand jury not endorse the Government’s post-indictment factual averment that some individual Stryker Biotech employee acted with criminal *mens rea* in connection with the filing of the 2007 Annual Report, but moreover, the Presentment Clause further prohibits “the government from changing its approach midstream to rely on theories or evidence of which the indictment contained insufficient notice.” *United States v. Chase*, No. 2:04-CR-135, 2005 U.S. Dist. LEXIS 38337, at *11-12 (D. Vt. Nov. 30, 2005). That principle holds particularly true here, where the Government’s shifting factual theories appear tactically designed to evade both Stryker Biotech’s motion to dismiss and Defendants’ motions for severance.

Accordingly, the Court can and should disregard as a matter of law the Government’s post-indictment factual claim, not endorsed by the grand jury, that some yet-to-be identified individual Stryker Biotech employee acted with criminal *mens rea* in connection with the filing of the 2007 Annual Report. *See Gov’t Opp.* at 10-11.

IV. The Government's Opposition Confirms That Count 13 Is Not Properly Joined Under Rule 8(b).

The Government's Opposition raises further serious questions about its attempts to avoid Defendants' motion to sever Count 13.⁹ The Government has opposed the severance motion on the theory that Count 13 is an overt act in the conspiracy, but plainly that theory is flatly inconsistent with the Government's collective knowledge theory. It is well-settled that an act is an overt act in a conspiracy only if it is done in furtherance of the conspiracy; *i.e.*, "calculated to achieve some aim of the conspiracy." L. Sand, et al., *Modern Federal Jury Instructions* Inst. 19-8 (comment) (1984) (citing *Grunewald v. United States*, 353 U.S. 391, 414-15 (1957)). An act by a corporation where no employee intends to act wrongfully certainly cannot be "calculated to achieve some aim of the conspiracy."

The Government's vague assertions that there may be some yet-to-be identified Stryker Biotech employee whom the Government will show acted "knowingly and willfully" in connection with the filing of the 2007 Annual Report do not suffice. Rather, the Government's shifting theories and persistence in refusing to identify this supposed employee, who has failed to surface in the mountains of discovery and interview reports and a month before trial remains known only to the Government, raises more questions than it answers. The Government should not be permitted to salvage the misjoined Count 13 based on such thin arguments.

Though the Government's Opposition takes a detour through Defendant Mark Philip's alleged misconduct in or around October 2007, Mr. Philip's alleged conduct in October 2007 is not evidence that he or anyone else at Stryker Biotech possessed a Section 1001 *mens rea* six months earlier, on April 30, 2007, when the 2007 Annual Report was filed. Indeed, for all its

⁹ Stryker Biotech's motion to dismiss stands separate and apart from the severance motions on which this Court heard argument on November 9, 2011 (that is, severance of Count 13 does not turn upon the merits of Stryker Biotech's motion to dismiss). Nevertheless, the Government's opposition to Stryker Biotech's motion to dismiss confirms that Count 13 is misjoined under Rule 8(b).

focus on Mr. Philip's conduct in October 2007, the Government is careful *not* to allege that Mr. Philip "knowingly and willfully" made or approved the filing of a false statement "on or about April 30, 2007." Superseding Indictment, ¶ 68. This confirms what Defendants argued in their consolidated reply brief in support of their severance motions, which is that the Government is using the joinder of Count 13 to bootstrap into the trial inflammatory spoliation allegations against Mark Philip — allegations that, because they are embedded in the conspiracy charge, prejudicially redound against the three other individual defendants. *See* Dkt. #160, at 12 n.8.

Beyond these irrelevant allegations about Philip's conduct six months after the filing of the 2007 Annual Report, the Government is left only with the conclusory and ultimately meaningless assurance that it "expects to adduce evidence at trial in support of" the idea that some unidentified individual Stryker Biotech employee "knowingly and willfully" made a false statement to the FDA through the filing of the 2007 Annual Report. Gov't Opp. at 11. That is not nearly good enough to satisfy Rule 8(b) with respect to Count 13. Rather, as Defendants previously have demonstrated, for the joinder of Count 13 to survive Defendants' Rule 8(b) challenges, the Court must conclude that the Government has an objectively reasonable expectation of proving to a jury beyond a reasonable doubt that a natural person, with the calculated intent to further the fraud conspiracy charged in Count 1, knowingly and willfully made a false statement to the FDA through the filing of the 2007 Annual Report. *See* Dkt. #160, at 7-11. The Government's Opposition to Stryker Biotech's motion to dismiss confirms that there is no such basis, which is why the Superseding Indictment contains no such allegation.¹⁰

Thus, if the Court for any reason chooses not to dismiss Count 13, it should nevertheless sever it.

¹⁰ As discussed in Defendants' reply brief in support of their motions to sever, *see* Dkt. #162, Paragraph 59(f) of the Superseding Indictment alleges that the filing of the 2007 Annual Report was an "overt act" of the Count 1 conspiracy. Like Count 13's charging paragraphs, however, that overt allegation refers generally to "Stryker Biotech" and does not refer or allude to any natural person.

CONCLUSION

For the foregoing reasons, Stryker Biotech's motion to dismiss Count 13 should be GRANTED.

Respectfully submitted,

STRYKER BIOTECH, LLC

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DATED: December 12, 2011

CERTIFICATE OF SERVICE

I, Joshua S. Levy, hereby certify that this document, filed through the ECF system, will be served electronically to the registered participants identified on the Notice of Electronic Filing (“NEF”), and that paper copies will be sent via electronic mail to those identified on the NEF as non-registered participants on December 12, 2011.

/s/ Joshua S. Levy
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